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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,023	08/28/2003	Joel Racchini	LFS-5015USNP	1564
27777	7590	08/11/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			APANIUS, MICHAEL	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/653,023	Applicant(s) RACCHINI ET AL.	
	Examiner Michael Apanius	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20030828, 20040813, 20041206, 20041217, 20050203, 20050516, 20060216, 20060411</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to a system for extracting a bodily fluid sample and monitoring an analyte therein, classified in class 600, subclass 584.
 - II. Claims 12-23, drawn to a device and method for ISF extraction, classified in class 600, subclass 576.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not claim at least one pressure ring as claimed in the subcombination. The subcombination has separate utility such as use by itself.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Mayumi Maeda on 7/27/2006 a provisional election was made with traverse to prosecute the invention of Group II, claims 12-23.

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Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-11 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities:

- a. At paragraph 7, line 2, it appears that "includes" should be --include--.
- b. At paragraphs 34, 71 and 86, the blanks for the US serial numbers should be filled in.
- c. At paragraph 54, last line, it appears that "409" should be --410--.
- d. At paragraph 96, line 3, it appears that "140" should be --14)--.

Appropriate correction is required.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

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requested in correcting any errors of which applicant may become aware in the specification.

9. The amendment filed 11/15/2004 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: incorporating the provisional application constitutes new matter because the original disclosure did not incorporate the provisional application. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

10. Claims 12-23 are objected to because of the following informalities: at claims 12-14, 18 and 19, it appears that the recitations of "the pressure ring" should be --the at least one pressure ring-- and at claim 18, line 2, it appears that "the first biasing element" lacks proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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12. Claims 12-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (US 6,332,871).

13. Douglas discloses an ISF extraction device comprising: a penetration member (16) configured for penetrating a target site of a user's skin layer and, subsequently, residing in the user's skin layer (i.e. as shown in figures 4C-4E; paragraph bridging columns 5 and 6) and extracting an ISF sample therefrom; and pressure rings ((1, 25, 120 in figure 19B)) adapted for applying pressure to the user's skin layer in the vicinity of the target site while the penetration member is residing in the user's skin layer, wherein the ISF extraction device is configured such that the pressure rings are capable of applying the pressure in an oscillating manner (column 6, lines 16-18) whereby an ISF glucose lag of the ISF sample extracted by the penetration member is mitigated. Note that the applied pressure will inherently mitigate an ISF glucose lag.

14. In regards to claims 13 and 22, one of the pressure rings applies pressure for a time period, subsequently removes pressure for the time period, and then reapplied pressure for the time period, wherein the time period is in the range from three seconds to three hours. Note that Douglas teaches oscillations at a minimum of 2 cycles per minute. Oscillations at 2 cycles per minute will have time periods of at least 3 seconds. During each oscillation, the pressure will be applied and then removed.

15. In regards to claim 14, the device further comprises a first biasing member (299 in figure 19B) configured for moving the pressure ring between a deployed state and a retracted state; and a second biasing member (11) configured for launching the penetration member.

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16. In regards to claim 15, the penetration member is capable of residing in the user's skin layer for a period of at least 1 hour. Note that the time durations are user inputs and therefore the time duration can be set for any time period including at least 1 hour (column 7, lines 7-9).

17. In regards to claims 16, 17, 20 and 21, the device has three concentrically arranged pressure rings (1, 25, 120 in figure 19B).

18. In regards to claim 18, the pressure rings and first biasing element are inherently capable of applying a pressure in the range of 0.1 to 150 pounds per square inch to a use's skin layer.

19. In regards to claim 19, the limitations are disclosed in the use of the device noted above.

20. In regards to claim 23, the pressure may alternatively be applied in an asymmetric oscillating manner (for example a wobbling motion; column 7, lines 11-12).

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

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by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

22. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

23. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 12, 13, 15, 16, 17, 18 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 46-50 and 55, respectively, of copending Application No. 10/882,994. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the instant claims because the copending claims recite all of the limitations of the corresponding instant claims. Therefore, the two sets of claims are not patentably distinct. Note that the copending claims do not expressly state that an ISF glucose lag is mitigated. However, the copending claims will

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inherently mitigate an ISF glucose lag during normal operation of the copending claimed inventions. In regards to copending claim 35, note that the device of the copending claims is capable of applying pressure in an oscillating manner because it can impart translational motion in opposite directions. In regards to copending claim 55, note that the 3 translating steps are considered applying pressure in an oscillating manner. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,857,983 discloses method and apparatus for sampling body fluid. US 6,706,159 discloses a combined lancet and electrochemical analyte-testing apparatus.


26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA


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